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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,615	11/13/2000	Kenneth F. Buechler	230/006	4653

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EXAMINER

COOK, LISA V

ART UNIT	PAPER NUMBER
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1641

19

DATE MAILED: 05/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/712,615

Applicant(s)

BUECHLER ET AL.

Examiner

Lisa V. Cook

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 21 December 2002.

2a) ☒ This action is **FINAL**.

2b) ☒ This action is non-final. *✓ Cook 8/14/03*

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 27,28 and 93-108 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 27,28 and 93-108 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) ☐ Interview Summary (PTO-413) Paper No(s). _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action (Appeal Brief filed 12/24/02) is persuasive and, therefore, the finality of that action is withdrawn. Claims 27-28 and 93-108 are pending and under consideration.

OBJECTIONS MAINTAINED

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

3. The information disclosure statements filed 6/25/01-Paper #6, has not been considered as to the merits prior to first action because the Information Disclosure Statement under 37 CFR 1.56 was not signed. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Applicant contends that the Information Disclosure Statement was previously submitted in the parent application and should therefore be considered by the examiner without a signature. This argument was carefully considered but not found persuasive because 37 CFR 1.1-2(b) requires a signature for each file. The objection is maintained.

Since each file must be complete in itself, a separate copy of every paper to be filed in a patent or trademark application, patent file, trademark registration file, or other proceeding must be furnished for each file to which the paper pertains, even though the contents of the papers filed in two or more files may be identical. The filing of duplicate copies of correspondence in the file of an application, patent, trademark registration file, or other proceeding should be avoided, except in situations in which the Office requires the filing of duplicate copies. The Office may dispose of duplicate copies of correspondence in the file of an application, patent, trademark registration file, or other proceeding.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 28 and 101-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 28 and 101-108 the use of "timing zone" is vague and indefinite because it is not clear as to what the term is to encompass. Is the zone merely to evaluate the reactions end wherein a signal is evaluated with respect to reagent flow? As recited the term "timing zone" is a relative term, which renders the claim indefinite. The term "timing zone" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 27, 28, and 93-108 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All the claims are directed to device configured to include at least one timing zone. The timing zone allows the device (claim 27) and kit (claim 28) to measure or determine the progress and time of completion of an assay for an analyte of interest in the via the timing zone signal. However support for the “timing zone” is not found in the instant disclosure. Applicant is invited to show support for the “timing zone” in the instant application.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 27, 93, 94, 96, 97, 98, 99, and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. (U.S. Patent #5,132,097).

Buechler discloses assay devices meeting the requirements of the instant invention. This is supported by the specification on page 59, lines 21-28. Particularly Buechler's device comprises a reaction chamber (column 6) and a diagnostic lane (column 10 –diagnostic element). See figures 1-5, item #4 (reaction chamber, column 6 and 7), item #17 (optional reagent chambers, column 8 and 9, and item # 6 (diagnostic element, column 10). The device includes a time gate for measuring the reaction in a given period of time. Please see column 7 lines 41-45. The device is useful in measuring an absolute signal or a rate of change of the signal. Particularly determining the presence or amount of each target ligand in the sample either visually or instrumentally. Column 17, lines 44-46. The rate of change is monitored via the flow rate of reagents through the porous member. Column 18, lines 2-9. Further the label (signal development element) does not appreciably bind to any reagent in said assay device but could be designed to indirectly cause a visually or instrumentally detectable signal as a result of the assay process. Column 3, lines 17-25. The apparatus of Buechler further includes an optical system for detecting and processing optical signals generated from the label in the diagnostic lane. Column 20 lines 22-31.

Buechler differs from the instant invention in not specifically disclosing the detailed structure of the optical system including an optical component and a signal processor specifically configured to read electronic signals.

However, such an optical system is considered conventional in the assay art, see Van Deusen et al. Van Deusen et al. teach devices having both an optical signal detector and signal processor. Van Deusen et al. disclose an apparatus for analyzing specific binding complexes. A test strip having a reactive surface coated with a specific binding member is employed and laser analysis allows for detection via a detector assembly (processor). See abstract, Column 2, 55-68 through column 3, lines 1-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure optical signals via a signal processor as taught by Van Deusen et al. in the device as taught by Buechler to perform immunoassay detection procedures, because Van Deusen et al. taught that signal processors allowed for information gathering and dissemination. (Column 3, lines 33-35). Further such an optical detector and signal processor are always required in an optical system in order to detect and process the signals generated from the labels.

One having ordinary skill in the art would have been motivated to do this to greatly reduce the time required for analysis and improve reagent flow. Van Deusen Column 3, lines 20-21.

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II. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. as applied to claims 27, 93, 94, 96, 97, 98, 99, and 100 above, and further in view of Slovacek et al. (U.S. Patent#5,242,837).

Please see Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. as set forth above.

The primary references do not particularly exemplify the use of a fluorometer as a useful optical detector.

However, fluorometers are routinely utilized to detect specific binding reagents. This point is supported in the patent of Slovacek et al. Therefor the use of a fluorometer is routine optimizations that are almost always determined and used in immunoassay studies. Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different known detectors in the given parameters to determine the unknown as a means of optimizing the device provided by the art.

III. Claims 28 and 101, 102, and 104-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. as applied to claims 27, 83, 94, 96, and 98-100 above, and further in view of Zuk et al.(U.S.Patent#4,281,061).

The teachings of Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. are set forth above. However, these references fail to teach the assay as a kit.

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Zuk et al. (4,281,061) teach that “as a matter of convenience the reagents [of an immunoassay] can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest” (column 22, lines 63-66).

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant’s invention to take the detection assay device as taught Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. and format it into a kit because Zuk et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Although the reference does not specifically disclose that a kit would have instructions which teach how to use said kit, it would have been prima facie obvious to any one of ordinary skill in the art to include instructions which describe how to perform the assay. Applicants should note that the printed matter on the instructions in a kit cannot serve to define the kit over the prior art. See in re Gulack 217 USPQ (CAFC 1983).

IV. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. and in further view of in view of Zuk et al.(U.S.Patent#4,281,061) as applied to claims 28 and 101, 102, and 104-108 above, and further in view of Slovacek et al. (U.S. Patent#5,242,837).

Please see Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. and in further view of Zuk et al. as set forth above.

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The primary references do not particularly exemplify the use of a fluorometer as a useful optical detector.

However, fluorometers are routinely utilized to detect specific binding reagents. This point is supported in the patent of Slovacek et al. Therefor the use of a fluorometer is routine optimizations that are almost always determined and used in immunoassay studies. Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different known detectors in the given parameters to determine the unknown as a means of optimizing the device provided by the art.

V. Claims 27, 93, 94, 96, 97, 98, 99, and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over May et al. (U.S. Patent #6,187,598) in view of Van Deusen et al. (U.S. Patent #5,132,097).

May et al. disclose assay devices meeting the requirements of the instant invention. This supported by the specification on page 59, lines 21-28. In one embodiment of the invention the reagent is not the analyte of interest, but an analyte analogue (is a chemical entity having the identical specific binding characteristic as the analyte). The analogue moves independently and similarly to the analyte of interest. Column 2 lines 46 through column 3 line 7.

May et al. differ from the instant invention in not disclosing the device with an optical component and a signal processor specifically configured to read electronic signals.

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Van Deusen et al. teach devices having both an optical signal detector and signal processor. Van Deusen et al. disclose an apparatus for analyzing specific binding complexes. A test strip having a reactive surface coated with a specific binding member is employed and laser analysis allows for detection via a detector assembly (processor). See abstract, Column 2, 55-68 through column 3, lines 1-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure optical signals via a signal processor as taught by Van Deusen et al. in the device of May et al. to perform immunoassay detection procedures, because diagnostic lanes (with reagent and timing zones) as taught by Sheppard were ideal in controlling sample flow and monitoring reagent use. See Sheppard et al. column 19 through column 20. Also the signal and processors as taught by Van Deusen et al. were well known in the art at the time of the instant invention. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing such systems, because Van Deusen et al. taught that signal processors allowed for information gathering and dissemination. (Column 3, lines 33-35).

One having ordinary skill in the art would have been motivated to do this to greatly reduce the time required for analysis. Column 3, lines 20 -21.

VI. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over May et al. (U.S. Patent #6,187,598) in view of Van Deusen et al. as applied to claims 27, 93, 94, 96, 97, 98, 99, and 100 above, and further in view of Slovacek et al. (U.S. Patent#5,242,837).

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Please see May et al. (U.S. Patent #6,187,598) in view of Van Deusen et al. as set forth above.

The primary references do not particularly exemplify the use of a fluorometer as a useful optical detector.

However, fluorometers are routinely utilized to detect specific binding reagents. This point is supported in the patent of Slovacek et al. Therefor the use of a fluorometer is routine optimizations that are almost always determined and used in immunoassay studies. Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different known detectors in the given parameters to determine the unknown as a means of optimizing the device provided by the art.

VII. Claims 28 and 101, 102, and 104-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over May et al. (U.S. Patent #6,187,598) in view of Van Deusen et al. (U.S. Patent #5,132,097) as applied to claims 27, 83, 94, 96, and 98-100 above, and further in view of Zuk et al.(U.S.Patent#4,281,061).

The teachings of May et al. (U.S. Patent #6,187,598) in view of Van Deusen et al. (U.S. patent #6,143,247) are set forth above. However, these references fail to teach the assay as a kit.

Zuk et al. (4,281,061) teach that “as a matter of convenience the reagents [of an immunoassay} can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest” (column 22, lines 63-66).

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It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay device as taught by May et al. in view of Van Deusen et al. (U.S. Patent #5,132,097) and format it into a kit because Zuk et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Although the reference does not specifically disclose that a kit would have instructions which teach how to use said kit, it would have been prima facie obvious to any one of ordinary skill in the art to include instructions which describe how to perform the assay. Applicants should note that the printed matter on the instructions in a kit cannot serve to define the kit over the prior art. See *in re Gulack* 217 USPQ (CAFC 1983).

VIII. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over May et al. (U.S. Patent #6,187,598) in view of Van Deusen et al. and in further view of in view of Zuk et al. (U.S. Patent #4,281,061) as applied to claims 28 and 101, 102, and 104-108 above, and further in view of Slovacek et al. (U.S. Patent #5,242,837).

Please see May et al. (U.S. Patent #6,187,598) in view of Van Deusen et al. and in further view of Zuk et al. as set forth above.

The primary references do not particularly exemplify the use of a fluorometer as a useful optical detector.

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However, fluorometers are routinely utilized to detect specific binding reagents. This point is supported in the patent of Slovacek et al. Therefore the use of a fluorometer is routine optimizations that are almost always determined and used in immunoassay studies. Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different known detectors in the given parameters to determine the unknown as a means of optimizing the device provided by the art.


7. For reasons aforementioned, no claims are allowed.
8. **THIS ACTION IS MADE NON-FINAL.** Examiner apologizes for any inconvenience to Applicant.
9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

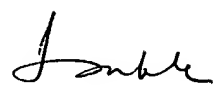
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Lisa V. Cook
CM1-7B17
(703) 305-0808
3/21/03


LONG V. LE
SUPERVISORY PATENT EXAMINER
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02/27/03